

**House File 2075 - Introduced**

HOUSE FILE 2075  
BY COMMITTEE ON COMMERCE

(SUCCESSOR TO HSB 530)

**A BILL FOR**

1 An Act requiring health benefit coverage for certain cancer  
2 treatment delivered pursuant to approved cancer clinical  
3 trials and providing an applicability date.  
4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 514C.26 **Approved cancer clinical**  
2 **trials coverage.**

3 1. *Definitions.* For purposes of this section, unless the  
4 context otherwise requires:

5 a. "*Approved cancer clinical trial*" means a scientific  
6 study of a new therapy for the treatment of cancer in human  
7 beings that meets the requirements set forth in subsection 3  
8 and consists of a scientific plan of treatment that includes  
9 specified goals, a rationale and background for the plan,  
10 criteria for patient selection, specific directions for  
11 administering therapy and monitoring patients, a definition of  
12 quantitative measures for determining treatment response, and  
13 methods for documenting and treating adverse reactions.

14 b. "*Institutional review board*" means a board, committee, or  
15 other group formally designated by an institution and approved  
16 by the national institutes of health, office for protection  
17 from research risks, to review, approve the initiation of,  
18 and conduct periodic review of biomedical research involving  
19 human subjects. "Institutional review board" means the same  
20 as "institutional review committee" as used in section 520(g)  
21 of the federal Food, Drug, and Cosmetic Act, as codified in 21  
22 U.S.C. § 301 et seq.

23 c. "*Routine patient care costs*" means medically necessary  
24 services or treatments that are a benefit under a contract  
25 or policy providing for third-party payment or prepayment of  
26 health or medical expenses that would be covered if the patient  
27 were receiving standard cancer treatment. "*Routine patient care*  
28 *costs*" does not include any of the following:

29 (1) Costs of any treatments, procedures, drugs, devices,  
30 services, or items that are the subject of the approved  
31 cancer clinical trial or any other investigational treatments,  
32 procedures, drugs, devices, services, or items.

33 (2) Costs of nonhealth care services that the patient  
34 is required to receive as a result of participation in the  
35 approved cancer clinical trial.

1 (3) Costs associated with managing the research that is  
2 associated with the approved cancer clinical trial.

3 (4) Costs that would not be covered by the third-party  
4 payment provider if noninvestigational treatments were  
5 provided.

6 (5) Costs of any services, procedures, or tests provided  
7 solely to satisfy data collection and analysis needs that are  
8 not used in the direct clinical management of the patient  
9 participating in an approved cancer clinical trial.

10 (6) Costs paid for, or not charged for, by the approved  
11 cancer clinical trial providers.

12 (7) Costs for transportation, lodging, food, or other  
13 expenses for the patient, a family member, or a companion  
14 of the patient that are associated with travel to or from a  
15 facility where an approved cancer clinical trial is conducted.

16 (8) Costs for services, items, or drugs that are eligible  
17 for reimbursement from a source other than a patient's contract  
18 or policy providing for third-party payment or prepayment  
19 of health or medical expenses, including the sponsor of the  
20 approved cancer clinical trial.

21 (9) Costs associated with approved cancer clinical  
22 trials designed exclusively to test toxicity or disease  
23 pathophysiology.

24 *d. "Therapeutic intent"* means that a treatment is aimed  
25 at improving a patient's health outcome relative to either  
26 survival or quality of life.

27 2. *Coverage required.* Notwithstanding the uniformity of  
28 treatment requirements of section 514C.6, a policy or contract  
29 providing for third-party payment or prepayment of health or  
30 medical expenses shall provide coverage benefits for routine  
31 patient care costs incurred for cancer treatment in an approved  
32 cancer clinical trial to the same extent that such policy or  
33 contract provides coverage for treating any other sickness,  
34 injury, disease, or condition covered under the policy or  
35 contract, if the insured has been referred for such cancer

1 treatment by two physicians who specialize in oncology and  
2 the cancer treatment is given pursuant to an approved cancer  
3 clinical trial that meets the criteria set forth in subsection  
4 3. Services that are furnished without charge to a participant  
5 in the approved cancer clinical trial are not required to be  
6 covered as routine patient care costs pursuant to this section.

7 3. *Criteria.* Routine patient care costs for cancer  
8 treatment given pursuant to an approved cancer clinical  
9 trial shall be covered pursuant to this section if all of the  
10 following requirements are met:

11 a. The treatment is provided with therapeutic intent and is  
12 provided pursuant to an approved cancer clinical trial that has  
13 been authorized or approved by one of the following:

14 (1) The national institutes of health.

15 (2) The United States food and drug administration.

16 (3) The United States department of defense.

17 (4) The United States department of veterans affairs.

18 b. The proposed treatment has been reviewed and approved by  
19 the applicable qualified institutional review board.

20 c. The available clinical or preclinical data indicate  
21 that the treatment that will be provided pursuant to the  
22 approved cancer clinical trial will be at least as effective  
23 as the standard therapy and is anticipated to constitute an  
24 improvement in therapeutic effectiveness for the treatment of  
25 the disease in question.

26 4. *Notice.* As soon as practical after the insured  
27 provides written consent to participate in an approved cancer  
28 clinical trial, the physician shall provide notice to the  
29 third-party payment provider of the insured's intent to  
30 participate in an approved cancer clinical trial. Failure  
31 to provide such notice to the third-party payment provider  
32 shall not be the basis for denying the coverage required under  
33 subsection 2.

34 5. *Immunity.* A person issuing a third-party payment  
35 contract or policy shall not be liable for any damages to an

1 insured who participates in an approved cancer clinical trial  
2 arising out of participation in the clinical trial.

3 6. *Applicability.*

4 a. This section applies to the following classes of  
5 third-party payment provider contracts or policies delivered,  
6 issued for delivery, continued, or renewed in this state on or  
7 after July 1, 2010:

8 (1) Individual or group accident and sickness insurance  
9 providing coverage on an expense-incurred basis.

10 (2) An individual or group hospital or medical service  
11 contract issued pursuant to chapter 509, 514, or 514A.

12 (3) An individual or group health maintenance organization  
13 contract regulated under chapter 514B.

14 (4) Any other entity engaged in the business of insurance,  
15 risk transfer, or risk retention, which is subject to the  
16 jurisdiction of the commissioner.

17 (5) A plan established pursuant to chapter 509A for public  
18 employees.

19 (6) An organized delivery system licensed by the director  
20 of public health.

21 b. This section shall not apply to accident-only,  
22 specified disease, short-term hospital or medical, hospital  
23 confinement indemnity, credit, dental, vision, Medicare  
24 supplement, long-term care, basic hospital and medical-surgical  
25 expense coverage as defined by the commissioner, disability  
26 income insurance coverage, coverage issued as a supplement  
27 to liability insurance, workers' compensation or similar  
28 insurance, or automobile medical payment insurance.

29

EXPLANATION

30 This bill creates new Code section 514C.26 to require health  
31 benefit coverage for cancer treatment delivered pursuant to an  
32 approved cancer clinical trial. The bill defines "approved  
33 cancer clinical trial" as a scientific study of a new therapy  
34 for the treatment of cancer in human beings that meets  
35 requirements specified in the bill and consists of a scientific

1 plan of treatment.

2 The bill requires that a policy or contract provide health  
3 benefit coverage for routine patient care costs incurred for  
4 cancer treatment in an approved cancer clinical trial to the  
5 same extent that the policy or contract provides coverage for  
6 treating any other sickness, injury, disease, or condition  
7 covered under the policy or contract, if the insured has been  
8 referred for such cancer treatment by two physicians who  
9 specialize in oncology, and the cancer treatment is given  
10 pursuant to an approved cancer clinical trial as set forth in  
11 the bill.

12 The bill provides that after an insured receives written  
13 consent to participate in an approved cancer clinical trial,  
14 the physician shall provide notice to the third-party payment  
15 provider of the insured's intent to participate in the trial.  
16 Failure to provide such notice to the third-party payment  
17 provider cannot be the basis for denying coverage required  
18 under the bill.

19 The bill also provides that a person issuing a third-party  
20 payment contract or policy is not liable for any damages to any  
21 insured that arise out of participation in an approved cancer  
22 clinical trial.

23 The bill applies to specified classes of third-party payment  
24 provider contracts or policies delivered, issued for delivery,  
25 continued, or renewed in this state on or after July 1, 2010.